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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,054	04/20/2000	FRANK MAN-WOON NG	017227/0156	4140

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/11/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,054

Applicant(s)

NG et al.

Examiner

Christine Saoud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 3, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7-18, 34, 36, and 39-44 is/are pending in the application.
- 4a) Of the above, claim(s) 12, 14, 17, 18, 34, and 40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13, 16, 41, and 43 is/are allowed.
- 6) ☒ Claim(s) 1, 7-11, 15, 36, and 39 is/are rejected.
- 7) ☒ Claim(s) 42 and 44 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Claims 37-38 have been canceled, claims 1 and 15 have been amended, and claims 41-44 have been added as requested in the amendment of paper #18, filed 03 February 2003. Claims 7-18, 34, 36, 39-44 are pending in the instant application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed 03 February 2003 have been fully considered but they are not deemed to be persuasive.

Election/Restriction

5. Claims 17-18, 34 and 40 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 12.

Applicant's election of the peptide of SEQ ID NO:19 is noted in paper #14. Applicant urges that claims 8-10 and 15 correspond to the elected invention. Applicant's arguments are

persuasive for claims 8-10 and 15 in so far as the claims encompass the elected peptide of SEQ ID NO:19. Claims 12 and 14 do not encompass the elected peptide. Therefore, these claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made without traverse in Paper #14. Claims 1, 7-11, 13, 15, 16, 36-37 and 39 are under examination.

Claim Rejections - 35 USC § 102

6. Claims 1, 7-11, 15, 36, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Wade et al. (Acta Endocrinologica 101: 10-14, 1982) for the reasons of record in paper #15..

Applicant argues that the Examiner has not provided evidence that an amide bond would be inherent in the peptide of Wade et al. This argument is persuasive with respect to an “amide bond”. However, the Examiner misstated the inherent property, which would be the salt bridge that would be naturally formed between the oppositely charged side chains of the arginine and glutamic acid residues, given the close proximity of these amino acids in the peptide.

It is noted that the instant specification at page 9, lines 5-9 indicates the presence of a salt bridge when the amino acids at positions 183 and 186 are Arg and Glu. Since the elected peptide is identical in amino acid structure to the peptide of the prior art in this region (differs at position 176), the presence of the salt bridge between Arg and Glu would be expected by one of ordinary skill in the art and therefore, considered an inherent property.

Applicant further argues that Wade et al. “only disclose synthetic copies of the naturally occurring form of the carboxy terminus, not analogues of the carboxy terminus”. This argument

is not persuasive because the peptide itself is considered the “analogue of the carboxyl-terminal sequence of a growth hormone”. Therefore, the limitation (iii) of claim 1 would need to be inherent since the amino acid structure is the same and the specification fails to indicate any particular specifics in the method of preparation which would lead to altered inter amino acid bonds compared to the prior art.

7. Applicant’s arguments regarding the unexpected results with regard to the species of SEQ ID NO:19 are persuasive.

Allowable Subject Matter

8. Claims 42 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 13, 16, 41 and 43 are allowed.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 3PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud